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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/665,742

**Applicant(s)**

BOLMSJO ET AL.

**Examiner**

Adam Marcetich

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,8-12,20-27,30,31,33-38,40,44,45 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8-12,20-27,30,31,33-38,40,44,45 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1,5,8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US 6494855) in view of Ressemann; Thomas V. et al. (US 5466222).
  4. Regarding claim 1, Rioux discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an

urine drainage interior passageway extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (column 7, lines 40-42 and Fig. 3, inflatable balloon 1); and

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1).

Rioux discloses the invention as substantially claimed, see above. However, Rioux lacks a coiled section of an inflation tube as claimed [claim 1]. Ressemann discloses an intravascular balloon catheter (col. 2, lines 34-43, col. 3, lines 42-52, Fig. 1, catheter 10) comprising a balloon (col. 5, lines 5-18, inflation lumen 33 at proximal end) and helical inflation tube (col. 5, lines 5-18, Fig. 5, helical tube 31). Ressemann further discloses:

a coiled section of the inflation tube formed at a position along the inflation tube (col. 5, lines 5-18, Fig. 5, helical tube 31);

to locate the coiled section within the urinary canal adjacent to and proximal of the sphincter muscle when the main body is located in the use position (it is the Examiner's position that modifying Rioux in view of Ressemann places helical tube 31 of Ressemann adjacent to and proximal of the sphincter muscle);

the coiled section interacting with a constriction of the urinary tract by the sphincter muscle to restrain the main body against distal movement within the urinary tract from the use position (Fig. 5, helical tube 31 capable of maintaining axial shape and therefore restraining against distal movement). One would be motivated to modify Rioux with the coiled section as taught by Ressemann to anchor a urinary catheter since both Rioux and Ressemann anchor a catheter within a tubular physiologic vessel. That is, Rioux anchors a catheter within the urethra and Ressemann anchors a catheter within a blood vessel. Additionally, Ressemann discloses helical tube 31 as performing an anchoring function (cols. 7-8, lines 56-6, especially lines 67-2, catheter locked in extended position). Ressemann provides the advantage of providing a second function with the same part of a balloon catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the coiled section of inflation tube as taught by Ressemann in order to consolidate the number of parts while both inflating a lumen and anchoring a catheter.

5. Regarding claim 5, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section comprising a plurality of individual adjacent coils each formed by the inflation tube as claimed [claim 5]. Ressemann discloses a coiled section comprising a plurality of individual adjacent coils (Fig. 5, helical tube 31 depicted as plurality of coils). Regarding rationale and motivation, see discussion of claim 1 above.

6. Regarding claims 8 and 9, Rioux discloses the invention substantially as claimed, including a main body having an outer or exterior transverse dimension. See above. However, Rioux lacks a coiled section as claimed [claims 8 and 9]. Ressemann discloses a coiled section, as discussed for claim 1 above, including an outer transverse dimension and a center opening (Fig. 5, helical coil 31 having outer transverse dimension and center opening for passage of actuating member 16). In modifying the invention of Rioux in view of Ressemann, the main body as taught by Rioux is surrounded by the coil as taught by Ressemann. Therefore, the combined invention demonstrates both:

[8] an outer transverse dimension of the coiled section greater than the outer transverse dimension of the main body; and

[9] an inner transverse dimension of the coiled section substantially the same as the exterior transverse dimension of the main body.

An outer transverse dimension of a coiled section needs to be greater than the outer transverse dimension of the main body in order to be placed in a surrounding manner. In other words, this property naturally follows from placing a coiled section

about a main body. Also, Ressemann provides the advantage of compact design, which conserves space inside a physiological lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the coiled section having an outer or exterior transverse dimension as taught by Ressemann in order to conserve space.

7. Claims 10-12,20-26,30,31,33-37,40,44,45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US 6494855) in view of Ressemann; Thomas V. et al. (US 5466222), further in view of Devonec (US 6290666).

8. Regarding claims 10-12,20-26,30,31,35-37,40,45 and 47, Rioux in view of Ressemann discloses the invention substantially as claimed, see above. However, Rioux in view of Ressemann lacks an insertion tool and cord as claimed [claims 10-16 and 19]. Rioux discloses a "pusher" used for placing a main body (col. 9, lines 23-30), although the disclosure is silent regarding its structure. In other words, the "pusher" of Rioux suggests the structure of an insertion tool, although Rioux is silent regarding the structure of a length sufficient to position its first end within a urinary tract. Devonec discloses an endo-urethral prosthesis placeable without endoscopic or radiological checks (col. 2, lines 36-40, col. 3, lines 17-24) further comprising:

[10, 20] an insertion tool for connection to the indwelling catheter to move the indwelling catheter within the urinary tract to the use position (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, mandrel 60 and pusher 63),

[10, 20] the insertion tool having first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (col. 6, lines 48-54, Fig. 9, assembly placed into bladder 2). To clarify, the invention of Rioux in view of Ressemann as discussed is modified with the insertion tool as taught by Devonec.

Additionally, Devonec discloses:

[10, 20] an insertion tool extending through the center opening of a coiled section (cols. 5-6, lines 53-58, 66-2, Fig. 13, coil 52);

[11] an insertion tool having an exterior transverse dimension substantially the same as the exterior transverse dimension of the main body (Figs. 8a, 9, 10, pusher 63 and tubular element 11 having substantially same exterior transverse dimensions);

[12, 21] a separable connection that permits disconnection of the indwelling catheter and the insertion tool upon locating the indwelling catheter in the use position (col. 6, lines 13-31, especially lines 16-25, Fig. 8b, mandrel 60 engaging prosthesis 8);

[22] a separable connection retaining the main body to the insertion tool to permit movement of the insertion tool and the indwelling catheter as a unit when positioning the indwelling catheter in the use position (col. 6, lines 48-54, Fig. 8a, mandrel 60 and pusher 63 joined to prosthesis 8, forming assembly for insertion into bladder 2);

[22] the separable connection permits separation of a main body from the insertion tool in response to continued proximal movement of the insertion tool when the expanded balloon restrains the main body against proximal movement from the use position (col. 6, lines 59-4, Figs. 9-12, withdrawing mandrel 60 and pusher 63 from

prosthesis 8. To clarify, Rioux teaches a balloon as discussed for claim 1 above. Rioux in view of Ressemann is modified with the insertion tool as taught by Devonec.);

[25, 35] a separable connection including a selectively disconnectable bridging structure extending between the main body and the insertion tool (col. 6, lines 48-54, Fig. 8a, mandrel 60 within pusher 63);

[25, 35] the bridging structure fastening the main body to the insertion tool when connected (Fig. 8a, tubular element 11 fastened to pusher 63 as depicted);

[25, 35] the bridging structure releasing the main body from the insertion tool when the bridging structure is disconnected to permit separation of the indwelling catheter from the insertion tool in response to continued proximal movement of the insertion tool when the expanded balloon restrains the main body against proximal movement from the use position (col. 6, lines 55-62, mandrel 60 released and withdrawn, leaving tubular element 11 in place. Regarding an expanded balloon restraining the main body against proximal movement, Rioux teaches a balloon as discussed for claim 1 above. Rioux in view of Ressemann is further modified by mandrel 60 of Devonec.);

[26, 36] a selectively disconnectable bridging structure comprising a cord which extends between the main body and the insertion tool when the bridging structure connects the main body to the bridging structure (col. 5, lines 36-39, cols. 6-7, lines 63-4, Figs. 8a, 8b, 9-12, removal thread 14 extending between prosthesis 8 and mandrel 60 and pusher 63);

[26, 36] the extension of the cord between the main body and the insertion tool is eliminated when the bridging structure is disconnected (Fig. 12, mandrel 60 and pusher 63 removed);

[23, 24, 45] the insertion tool is removable from within the coiled section in response to a predetermined amount of proximal movement of the insertion tool in the urinary canal relative to the main body after separation at the separable connection, and the coiled section permits substantially unimpeded proximal movement of the insertion tool within the coiled section after separation at the separable connection (col. 6, lines 59-4, Figs. 9-12, mandrel 60 and pusher 63 withdrawn from prosthesis 8. It is the Examiner's position that helical tube 31 of Ressemann will not impede proximal movement of an insertion tool, since it surrounds mandrel 60 and pusher 63 of Devonec in the modified device.);

[30, 37, 40] the insertion tool defines an interior channel extending between the first and second opposite ends of the insertion tool (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, both mandrel 60 and pusher 63 comprising hollow tubes);  
and

[30, 37, 40] the interior channel of the insertion tool is in fluid communication with the interior passageway of the main body when the insertion tool is connected to the indwelling catheter at the separable connection (col. 6, lines 13-31, especially lines 16-25, Figs. 8a, 8b, 9-12, mandrel 60 placed within prosthesis 8);

[31, 47] the coiled section maintains a portion of the inflation tube between the coiled section and the proximal end of the main body substantially in alignment with a

portion of the insertion tool during movement of the indwelling catheter and the insertion tool as a unit within the urinary tract to the use position (col. 6, lines 13-31, especially lines 22-25, mandrel 60 inserted within prosthesis 8; also aligning with eyelet 62a. It is the Examiner's position that a helical tube 31 of Ressemann placed to surround a main body will also be concentric and maintain alignment.);

9. Regarding claims 33 and 44, Rioux in view of Ressemann in view of Devonec discloses the invention as substantially claimed. To clarify, Rioux discloses a main body and inflation tube. Ressemann coiled inflation tube. Devonec discloses an insertion tool having a substantially equal diameter to a main body. Devonec discloses an insertion tool having an exterior surface (Figs. 8a, 8b, 9-12, pusher 63 having exterior surface). The invention of Rioux in view of Ressemann modified with the insertion tool as taught by Devonec substantially forms an inflation tube extending along the exterior surface of an insertion tool when the main body is connected to the insertion tool. Regarding rationale and motivation, see discussion of claim 10 above.

10. Regarding claim 34, Rioux discloses an assembly of an indwelling catheter used to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, the assembly comprising:

a main body of the indwelling catheter, the catheter main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the catheter main body defining an urine drainage interior passageway

extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the catheter main body, the balloon expandable in size within the bladder (column 7, lines 40-42 and Fig. 3, inflatable balloon 1);

an inflation tube having a distal end, a proximal end and a length extending between the distal and proximal ends, the distal end connected to the catheter main body, the length sufficient to extend from the catheter main body through the urinary canal to the exterior opening when the indwelling catheter is located in the use position, the inflation tube and the catheter main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1);

Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section of inflation tube, an insertion tool, a separable connection between the catheter main body and the tool main body, and a selectively disconnectable bridging structure as claimed [claim 34]. Ressemann discloses a coiled section of inflation tube as discussed for claim 1 above. In these grounds of rejection, the inflation tube as taught by Rioux is modified with a coiled shape as taught by Ressemann. It is the Examiner's position that the coiled section of Rioux in view of Ressemann is capable of interacting with a constriction of the urinary tract by the sphincter muscle to restrain the catheter main body against distal movement within the

urinary tract from the use position. Additionally, Norton et al. (US 4,531,933) and Huxel et al. (US 2002/0002399) provide further examples of a coiling structure used to restrain an endourethral implant. Norton and Huxel are not relied upon for teaching limitations in these grounds of rejection, and are only provided as additional examples.

Rioux in view of Ressemann discloses the invention substantially as claimed, see above. However, Rioux in view of Ressemann lacks an insertion tool as claimed [claim 34]. Rioux calls for a "pusher" used for placing a main body (col. 9, lines 23-30), although Rioux is silent regarding its structure. Devonec discloses:

a main body of an insertion tool, the tool main body first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, mandrel 60 and pusher 63); and

a separable connection between the catheter main body and the tool main body, the separable connection maintaining the insertion tool connected to the indwelling catheter for movement as a unit when positioning the indwelling catheter in a use position, the use position locating the distal end of the catheter main body in the bladder and the proximal end of the catheter main body adjacent to and distal of the sphincter muscle (col. 6, lines 48-54, Fig. 8a, mandrel 60 and pusher 63 joined to prosthesis 8, forming assembly for insertion into bladder 2);

the separable connection permitting selective separation of the tool main body from the catheter main body in response to proximal movement of the insertion tool when the expanded balloon restrains the catheter main body against proximal

movement from the use position (col. 6, lines 59-4, Figs. 9-12, withdrawing mandrel 60 and pusher 63 from prosthesis 8. To clarify, the invention of Rioux is relied upon for a balloon as discussed. Rioux in view of Ressemann is further modified with the insertion tool as taught by Devonec.);

Regarding the limitation of a coiled section of the inflation tube winding around the insertion tool when the insertion tool is connected to the indwelling catheter, Rioux teaches an indwelling catheter and inflation tube, while Ressemann teaches an example of a coiled inflation tube. Further, Devonec discloses an insertion tool extending through the center opening of a coiled section (cols. 5-6, lines 53-58, 66-2, Fig. 13, coil 52). In other words, Devonec teaches that mandrel 60 is placed within tubular segment 11 of prosthesis 8, which comprises a coil 52, which suggests placing an insertion tool within a coiled section. Regarding rationale and motivation to modify Rioux in view of Ressemann and further in view of Devonec, see discussion of claims 1 and 10 above.

11. Claims 27 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US 6,494,855) in view of Ressemann; Thomas V. et al. (US 5466222), in view of Devonec (US 6,290,666), further in view of C, Ewers Richard (US 2001/0056273, herein "Ewers").

12. Regarding claims 27 and 38, Rioux in view of Ressemann in view of Devonec discloses the invention substantially as claimed, including a cord (Devonec, Figs. 8a, 8b, 9-12, removal thread 14). See above. Additionally, Devonec discloses:

[27] an insertion tool defining an interior channel extending between the first and second opposite ends of the insertion tool (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, both mandrel 60 and pusher 63 comprising hollow tubes); and

[27] the interior channel of the insertion tool is in fluid communication with the interior passageway of the main body when the insertion tool is connected to the indwelling catheter at the separable connection (col. 6, lines 13-31, especially lines 16-25, Figs. 8a, 8b, 9-12, mandrel 60 placed within prosthesis 8).

However, Rioux in view of Ressemann in view of Devonec lacks a cord extending through the interior channel of an insertion tool as claimed [claims 27 and 38]. In other words, Devonec is silent regarding the placement of removal thread 14 within the lumen of a tube. Ewers discloses a catheter assembly suitable for placement within a urethra (¶ [0044], [0045]), further comprising a cord also extending through an interior channel to the second end of an insertion tool (¶ [0046], [0048], [0051], Figs. 3-5, suture 34 substantially extending through tube 14 to second end). To clarify, the invention of Rioux, Ressemann and Devonec as discussed is modified in view of the cord positioned within the lumen of a tube as taught by Ewers. Ewers provides the advantage of a compact design avoiding interaction between pulling a cord and patient tissues. In other words, placing a cord within a tube avoids potential abrasion between a cord and the inner urethral surface. Therefore, it would have been obvious to one of ordinary skill in

the art at the time the invention was made to modify the invention of Rioux in view of Ressemann in view of Devonec as discussed with the cord extending through an interior channel as taught by Ewers in order to avoid potential abrasion.

### ***Response to Arguments***

13. Applicant's arguments, see p. 10-18 filed 21 January 2009 with respect to the rejection(s) of claim(s) 1, 5, 8-12, 20-27, 30, 31, 33-38, 40, 44, 45 and 47 under 35 USC § 103 over Rioux, Anderson, Devonec and Ewers have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Rioux, Ressemann, Devonec and Ewers.

14. Applicant asserts that the provisional double patenting rejection of claim 1 should be withdrawn since claims 1, 16 and 17 of application 10/921,356 have been canceled or amended away from the immediate application. Examiner notes that the double patenting rejections have been withdrawn in view of these changes.

15. Applicant contends that the rejection of Rioux in view of Anderson is improper, since neither Rioux nor Anderson uses a portion of an inflation tube for a restraint. Applicant notes that Rioux lacks a single component which achieves both of the two previously-separate functions. In response, Examiner notes that Ressemann teaches an inflation tube (Fig. 5, helical tube 31 that both inflates a lumen and anchors a catheter, as discussed for claim 1 above.

16. Applicant reasons that motivation is lacking to combine Rioux in view of Anderson, and suggests that the rejection of claims 8 and 9 must be based on the impermissible use of hindsight. Examiner notes that Ressemann teaches a coiled inflation tube in the new grounds of rejection. It is the Examiner's position that placing helical tube 31 of Ressemann at a proximal location is a logical arrangement of components, since Ressemann uses helical tube 31 to anchor the catheter within a vessel.

17. Applicant asserts that the rejections of claims 10 and 34 and their dependents are improper, since the explanation in Devonec does not meet or comply with the claimed subject matter. Examiner notes that Rioux teaches an indwelling catheter having a balloon, and Devonec teaches an insertion tool. Regarding a length sufficient for positioning as claimed [claims 10 and 34], Denovec depicts mandrel 60 as extending between an external urethral opening and into the bladder (Figs. 9, 10). Therefore Examiner interprets the length of mandrel 60 as sufficient to be placed as claimed.

18. Applicant contends that the rejections of claims 10 and 34 and their dependents are improper, since the coiled reinforcing section of Devonec is located upstream of the external urinary sphincter muscle, while the coiled sections of the immediate invention is located downstream. Examiner notes that the coiled section of Devonec is provided as evidence that Devonec solves a similar problem. Instead, the helical tube 31 of Ressemann is relied upon as a downstream coil.

19. Applicant reasons that Devonec cannot describe the concept of disconnecting a separable connection in response to downstream movement when restrained by a

balloon, since Devonec lacks an expanded balloon. Examiner notes that Rioux teaches an expanded balloon. Additionally, Devonec teaches a catheter that is otherwise prevented from proximal movement, although by another means (col. 6, lines 55-58, Figs. 9, 10, prosthesis 8 held in place by pusher 63 while mandrel 60 is withdrawn).

20. Applicant asserts that Devonec's coiled section plays no role in aligning the inflation tube with the insertion tool, because the coil tube extends upstream, unlike Applicant's downstream inflation tube. Examiner notes that Ressemann teaches a coiled inflation tube in the new grounds of rejection. Additionally, helical tube 31 of Ressemann is depicted as downstream relative to a catheter distal end.

21. Applicant contends that Devonec lacks a cord which is a part of a selectively disconnectable bridging structure. Examiner notes that claims 26 and 36 recite ". . . a cord which extends between the main body and the insertion tool. . ." and that the language "which is part of" does not appear in the claims. Examiner interprets "extends between" broadly to include removal thread 14 as depicted by Devonec that extends between prosthesis 8 and mandrel 60. .

22. Applicant reasons that the thread described in Ewers interacts with completely different elements than those recited in claims 27 and 38, and for completely different purposes. Examiner notes that Applicant uses cord 90 to couple a main body to an insertion tool (specification p. 22, lines 3-10, 24-32), which effectively applies a proximal force on a distal catheter portion. Ewers solves both the problems of implanting a drainage catheter (§ [0044], [0045]) and applying a proximal force on an implanted catheter when it is deployed (§ [0051], [0059], Figs. 3-5, suture 34).

***Response to Declaration Under 37 CFR 1.132: Insufficient***

23. The declaration under 37 CFR 1.132 filed 21 January 2009 is sufficient to overcome the rejection of claims 1,5, 8-12, 20-27, 30, 31,33-38, 40, 44, 45 and 47 based upon 35 USC § 103 over Rioux, Anderson, Devonec and Ewers. Therefore, those rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Rioux, Ressemann, Devonec and Ewers.

24. The declaration includes statements which amount to an affirmation that the affiant has never seen the claimed subject matter before. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

25. Declarant reasons that since the retaining coils and loops described in the Norton and Anderson patents are located at opposite ends of urine drainage structures of both stents, it would have been impossible to include a coiled or looped section at both ends of the urine draining structure in our invention, because the urine draining structure must stop upstream of the external urinary sphincter muscle to allow the external urinary sphincter muscle to control urination. Examiner notes that Ressemann teaches a coil substantially at one end of an implanted catheter in the new grounds of rejection.

26. Declarant notes that neither Norton nor Anderson explains how an anchoring mechanism at opposite ends of the stent can be disassociated from the urine drainage structure to allow an external urinary sphincter muscle to control urine drainage.

Examiner notes that Rioux demonstrates a urine drainage structure that allows an external urinary sphincter muscle to control urine drainage.

27. Declarant notes that stents of the Norton and Anderson patents are intended to be inserted into the ureter which extends between the renal pelvis (kidney) and the bladder, and that the physiology of the kidney-bladder urine drainage function does not involve controlling urine by voluntarily opening a sphincter muscle. Declarant questions whether the coils, loops and curls discussed in Norton and Anderson would function in the environment of the urinary canal downstream of the external urinary sphincter muscle. Examiner notes that Norton and Anderson were previously submitted as teaching examples of coils used to restrain catheters within a urinary system. In the new grounds of rejection, Ressemann teaches an example of a coiled inflation tube used to anchor a catheter within a tubular vessel. Ressemann is relevant to the problem of anchoring a catheter, since helical tube 31 is disclosed as maintaining an axial dimension of a catheter.

28. Declarant reasons that the end coils, loops and curls shown in Norton and Anderson extend into an open volume of the kidney and the bladder, and that open volume is not comparable to the in the urethra downstream of the external urinary sphincter muscle where the restraint must be effective. Examiner notes that Anderson also shows coils contained within a tubular vessel (Figs. 1, 2, coiled section 12 within ureter 30). In the new grounds of rejection, Ressemann provides an example of a coiled inflation tube located within a vessel and also used for anchoring.

29. Declarant notes that Anderson describes loops and curls formed in a plane parallel to the axis of the center of coil which holds the ureter open. Declarant contends that the size of the loop, curl or J hook configuration achieves the restraint, as opposed to the effectiveness of the restraint in the confined surface of the urethra downstream of the external urinary sphincter muscle. Examiner notes that Ressemann teaches a coiled inflation tube located within the confined space of a vessel, and also lacks a terminal curl or J hook that might prevent inflation or interfere with a balloon.

30. Declarant notes that neither Norton nor Anderson describe an inflation tube. Examiner notes that Ressemann teaches a coiled inflation tube.

31. Declarant notes that the immediate invention also uses the inflation tube to remove the catheter, and that neither Norton nor Anderson disclose using the coiled tubes to remove a catheter. Examiner notes that the specification describes this function (p. 15, lines 11-13), although it does not appear in the claims.

**Conclusion**

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Hakki; A-Hamid et al. US 5569219
- ◆ Bonner, Jr.; Francis J. US 3894540
- ◆ Ressemann, Thomas V. et al. US 20020165574
- ◆ Wahr, Dennis W. et al. US 20020165598

33. Examiner has applied new grounds of rejection not necessitated by amendment. Therefore, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Adam Marcetich/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
25 March 2009